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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/562,397

06/09/2006

Richard Alexander Grant

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BANNER & WITCOFF, LTD.

1100 13th STREET, N.W.

SUITE 1200

WASHINGTON, DC 20005-4051

EXAMINER

SMITH, FANGEMONIQUE A

ART UNIT

PAPER NUMBER

3736

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/562,397	<b>Applicant(s)</b> GRANT ET AL.	
	<b>Examiner</b> FANGEMONIQUE SMITH	<b>Art Unit</b> 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-21 and 31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 and 31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

1. This Office Action is responsive to the Amendment filed on June 24, 2008. Examiner acknowledges the amendment of claims 1, 2, 6-8, 12, 15 and 21. Claims 1-21 and 31 are pending.

#### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-3, 5, 6, 8-13, 15-21 and 31 rejected under 35 U.S.C. 103(a) as being unpatentable over Parker et al. (U.S. Patent Number 5,279,796) in view of Lehtinen et al. (U.S. Patent Number 6,324,926).

In regard to claims 1-3, 5, 6, 8-13 and 31, Parker et al. disclose a disposable fluid sampling probe for aspirating fluid samples comprising a first portion (75) having a piercing head of a relatively small diameter needle for piercing a closed fluid carrier (63), and a second portion (16) serving as a reservoir for receiving a fluid. The second portion of the device disclosed by Parker et al. is operative with the first portion for piercing the closed fluid carrier. Parker et al. also disclose a third portion (80) providing fluid communication between the first and second portion. The second portion includes a disposable molded reservoir having a capacity sufficient for containing at least one sample volume of fluid. The disposable reservoir is joined to the first portion by an

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adhesive joint at the base of the support device and secured to the upper support of the device (col. 4, lines 61-68; col. 5, lines 1-60). The disposable molded reservoir is compressible and can accommodate a range of sample volumes (col. 4, lines 40-55). Parker et al. disclose the first portion being moveable with respect to the second portion such that, upon disengaging with the second portion, a fluid flow path is formed between a distal end of the second portion and the needle tip of the first portion. The second portion is a hollowed vessel which acts like an outer envelope for the received fluid and upon disengaging with the second portion, the second portion accommodates the needle therewithin (col. 5, lines 61-68; col. 6, lines 1-7). Parker et al. disclose the use of safety retaining clip (96) to secure the fluid sampling probe upon use of the system. In regard to claims 15-21, Parker et al. disclose a method of sampling a fluid from a closed fluid carrier using a probe including a first portion (75) for piercing a closed fluid carrier (63), a second portion (16) serving as a reservoir for receiving a fluid, and a third portion (80) providing fluid communication between the first and second portion. The method of using the Parker et al. device includes steps of axially extending the needle of the first probe portion to pierce the closed fluid carrier, advancing the first portion of the probe into contact with the fluid of the carrier and forming a fluid flow path between the fluid of the carrier and the second portion of the probe. Parker et al. further disclose steps of aspirating a volume of the fluid along the fluid flow path and retaining the volume of fluid within the second portion of the probe upon withdrawal of the probe from the carrier. The device disclosed by Parker et al. can be discarded or loaded again with another probe member. Upon removing the probe from the support member, Parker et al. disclose retracting the needle of the first portion to enclose the needle within the second portion of the device. Although Parker et al. disclose features of the

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Applicant's invention as described above, Parker et al. do not specifically disclose a second portion which serves as a reservoir for receiving an amount of fluid corresponding to a fluid sample from the closed fluid carrier as described by Applicant. Lehtinen et al. disclose a method and device for taking a sample from a closed tube. The device includes a needle for piercing a stopper of a test tube to obtain a sample of fluid from the closed tube. The sample of fluid is drawn into the sample receptacle of the sampling device through suction. It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify a disposable fluid sampling probe for aspirating fluid samples, similar to that disclosed by Parker et al., to include a sample receiving reservoir, similar to that disclosed by Lehtinen et al., to obtain a sample of fluid for testing while minimizing the risk of contamination.

4. Claims 4 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parker et al. (U.S. Patent Number 5,279,796) in view of Lehtinen et al. (U.S. Patent Number 6,324,926) and in further view of Lynn (U.S. Patent Number 6,740,063).

In regard to claims 4 and 14, the combined references of Parker et al. and Lehtinen et al. disclose the features of the Applicant's invention as described above. Although the combination discloses the use of a needle with the device, the combined references are silent to the size of the needle. Also, the combination does not disclose a Luer-type fitting being used to secure the fluid sampling probe to the fluid sampling system. Lynn discloses a catheter system for fluid connection between a patient's vasculature and a fluid system. The fluid system disclosed by Lynn includes a luer lock connector. Lynn also discloses the use of a 20 gauge needle with the system. It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify a disposable fluid sampling probe for aspirating fluid

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samples, similar to that disclosed by the combined references of Parker et al. and Lehtinen et al., to include a luer locking connector, similar to that disclosed by Lynn, to provide a different type of securing mechanism, while maintaining the functionality of the device. Additionally, it would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify a disposable fluid sampling probe for aspirating fluid samples, similar to that disclosed by the combined references of Parker et al. and Lehtinen et al., to include a 20 gauge needle, similar to that disclosed by Lynn, to adequately pierce seal of fluid carrier for fluid collection.

### ***Response to Arguments***

5. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fangemonique Smith whose telephone number is 571-272-8160. The examiner can normally be reached on Mon - Fri 8am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

FS

/Max Hindenburg/  
Supervisory Patent Examiner, Art Unit 3736